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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,505	10/18/2000	Marc K. Wallack	11221/5	5100

26646 7590 03/26/2002

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EXAMINER
BECKERLEG, ANNE M

ART UNIT	PAPER NUMBER
1632	10

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/691,504	WALLACK ET AL.	
	Examiner	Art Unit	
	Anne M Beckerleg	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17 and 54, drawn to antigen presenting cells infected with a vaccinia virus encoding an immunostimulatory molecule and methods of using said cells, classified in classes 435 and 424 , subclasses 325 and 93.2 respectively .

II. Claims 18-38 and 55-107, drawn to composition of vaccinia virus encoding a first immunostimulatory molecule and cells infected with a vaccinia virus encoding a second immunostimulatory molecule, and methods of using said composition, classified in classes 435 and 514, subclasses 320.1, 325 and 44.

III. Claims 1-17 and 39-53, drawn to antigen presenting cells infected with a vaccinia virus encoding an immunostimulatory molecule and methods of making said cells, classified in class 435, subclasses 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

2) Inventions I and III are distinct from invention II in that invention II includes a second independent vaccinia virus which encodes a different immunostimulatory molecule from that encoded by the vaccinia virus used to infect the antigen presenting cells. Further, the methods of immunizing using the compositions of invention II are substantially different from those of invention I in that invention II requires the direct administration of a vaccinia virus to a mammal. As such the methods utilize different substantially different reagents with substantially different biological functions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of immunostimulatory molecules of the claimed invention:

a) IL-2

b) IL-3

c) IL-4

d) IL-6

e) IL-7

f) IL-12

g) IL-15

h) IL-18

I) FLT-3/FLK-2 ligand

j) FLT-3 ligand

k) GM-CSF

l) G-CSF

m) stem cell factor

n) interferon

o) MAGE-1

p) MAGE-3

q) GAGE

r) BAGE

s) PRAME

t) NY-ESO-1

u) tyrosinase

v) Melan-A

w) MART-1

x) gp100

y) TRP-1

z) TRP-2

aa) MUM-1

ab) CDK4

ac) beta-catenin

ad) gp100in4

ae) p15

af) N-acetylglucosaminyltransferase

ag) B7-1

ah) TA-90

ai) lysosome-associate membrane protein

aj) melanocyte-stimulating hormone receptor

ak) p90

al) calnexin

Please note that the species identified above represent proteins with vastly different physical characteristics and biological properties.

If invention I or invention III is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of immunomodulotory molecule from the group a)-al) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1-4, 8-17 and 39-54 are generic.

If invention II is elected, Applicant is further required under 35 U.S.C. 121 to elect a first disclosed species from the group a)-al) for the first immunostimulatory molecule and a second

disclosed species from the group a)-al) for the second immunostimulatory molecule. Claims 18-22, 28-38, 55-63, 70-95, and 102-107 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Beckerleg

A.M.S. BECKERLEG
PATENT EXAMINER